Remarks

Rejection of Claims 1-11 Under 35 U.S.C. § 112 ¶ 1

The Final Office Action maintains the enablement rejection of claims 1-11. Applicants respectfully traverse the rejection.

As an initial matter, those portions of the rejection which are based on the recitation of "at least 95%, 98%, or 99% homology to the amino acid sequence SEQ ID NO:2" are mooted by cancellation of this recitation from the independent claims.

The enablement requirement of 35 U.S.C. § 112, first paragraph states that a patent specification must teach a person skilled in the relevant art how to make and use the invention claimed. Whether a specification enables a claimed invention is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991). The proper standard for determining whether the present specification meets the enablement requirement is whether any experimentation which may be needed to practice the methods of claims 19, 23-25, 30-46, and 49-57 is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided in the specification. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The Final Office Action repeats the assertion that neither the specification nor the art establishes a connection between FPRL1 and any specific cardiovascular disease condition. FPRL1 is highly expressed in cardiovascular related tissues, which indicates an association between FPRL1 and cardiovascular diseases (see the specification at page 57, lines 10-14). The Patent Office has not rebutted this teaching, which the Office must accept in the absence of

"acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

The Final Office Action has not met its burden of establishing a *prima facie* case of non-enablement. Please withdraw the rejection.

Rejection of Claims 1, 2, 4, 5, and 10 Under 35 U.S.C. § 102(b)

Claims 1, 2, 4, 5, and 10 stand rejected under 35 U.S.C. § 102(b) as anticipated by Gronert.[1] Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claims 1 and 2 each recite a step which refers to particular disorders which Gronert does not disclose.

Independent claim 1 recites a step of "identifying a test compound which binds to said FPRL1 polypeptide as a potential therapeutic agent useful in the treatment of the disease"; "the disease," as recited in claim 1, is "a disease selected from hematological diseases, cardiovascular diseases, disorders of the peripheral and central nervous system, respiratory diseases, COPD, asthma, and genito-urological disorders" as recited in the preamble of the claim.

Independent claim 2 recites a step of "identifying the test compound as a potential therapeutic agent useful in the treatment of the disease if the activity of the FPRL1 polypeptide is inhibited in the presence but not the absence of the test compound"; "the disease," as recited in claim 2, is "a disease selected from hematological diseases, cardiovascular diseases, disorders of the

[1] Gronert *et al.*, *J. Exp. Med. 187*, 1285-94, April 20, 1998.

peripheral and central nervous system, respiratory diseases, COPD, asthma, and genito-urological disorders" as recited in the preamble of the claim.

The Final Office Action gives no weight to the intended use recited in the preambles of claims 1 and 2 but ignores the fact that the disorders referred to in the preamble also are recited in the body of the claims. Gronert does not disclose any of the recited disorders, including the elected species of cardiovascular diseases. Gronert therefore does not anticipate independent claims 1 or 2 or dependent claims 4, 5, or 10.

Please withdraw the rejection.

Rejections Under 35 U.S.C. § 103(a)

The Final Office Action contains three rejections under 35 U.S.C. § 103(a), each based on Gronert as the primary reference:

- claims 1-6 and 8-10 over Gronert in view of Fiore;
- claim 7 over Gronert in view of Ramakrishnan; and
- claims 1 and 11 over Gronert in view of Seo.

A *prima facie* case of obviousness requires three elements:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P., 8th ed., § 2142. In this case, there is no *prima facie* case of obviousness at least because, as explained above, Gronert does not disclose a connection between the recited polypeptide and any of the diseases recited in the bodies of independent claims 1 and 2. None of the secondary

references remedies this deficiency. Thus, a *prima facie* case of obviousness has not been made over Gronert in view of any of the cited references.

Please withdraw the rejection.

Respectfully submitted,

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